

REMARKS

Claims 61-67, 71-73, 75-92, 97-100 and 102 presently appear in this case. Claims 66, 67, 69, 74-76, 82 and 83 have been withdrawn from consideration. No claim have been allowed. The official action of January 8, 2003, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a composition of matter consisting essentially of a mixture of at least about 50% of at least one liquid oil, such as fish oil, and 50% or less of beeswax.

The interview between Examiner Wang and the undersigned attorney on April 3, 2003, is hereby gratefully acknowledged. In this interview, proposed amendments to the claim language were discussed, as were the existing rejections of the claims. The arguments presented at the interview are set forth herein. The examiner agreed to consider such arguments carefully.

The examiner has examined the claims insofar as they read on the elected species. As the elected species will be shown to be allowable below, it is urged that the examiner consider and allow the claims now present in the case.

Claims 73 and 86 have been rejected under 35 U.S.C. §112, first paragraph. The examiner states that these claims recite a composition comprising 60% by weight of omega-3 polyunsaturated fatty acid (PUFA). The examiner states that natural fish oil only contains below 35% of omega-3 PUFA. The examiner states that applicant has failed to provide proper

guidance, direction or working examples for making refined fish oil with more than 60% by weight of omega-3 PUFA. This rejection is respectfully traversed.

The examiner states that a trademark, as set forth in Example 1 of the specification, is not considered a proper description for an ingredient that is essential for the claimed invention. However, the product in Example 1, EPAX7010 triglycerides, Pronova Biocare, is only one example of many products on the market having the required characteristics. The name "EPAX7010 triglycerides" is more than just a trademark. It is a description of the product. Attached hereto as Exhibit A is a page from the Pronova Biocare website that describes its products. This website states that the various EPAX products are described by a four-digit code indicating concentration, followed by a 2-letter code indicating the type of molecules in the product. It states that if the last two digits in the 4-digit code are "00", then the two first digits indicate the total concentration of omega-3 fatty acids in the product. Otherwise, the four-digit codes indicate the ratio of EPA and DHA. Thus, EPAX7010 triglycerides (TG) is a triglyceride product having 70% EPA and 10% DHA. Note that there are at least three other products on the website which have a concentration of 60% or more omega-3 fatty acid, i.e., EPAX 1050 TG, EPAX6000 TG and EPAX6000 EE.

Furthermore, this is not the only product on the market with greater than 60% omega-3 fatty acid. A review of the internet shows, for example, OmegaRx pharmaceutical grade

fish oil. At page 3 of the printout attached hereto as Exhibit B, it states that this product contains a minimum of 60% of long-chain omega-3 fatty acids, although it routinely reaches 75%. In the materials provided as an attachment to applicant's amendment of November 13, 2002, it is shown that fish oil concentrate 2050 TG contains total omega-3 fatty acids of a minimum of 80%. Thus, it is clear that there are many products on the market that have the required percentage of omega-3 fatty acids.

In the interview, the examiner stated that he could find no patents on concentrating the omega-3 fatty acid portion of fish oils. In this regard, the examiner's attention is invited to the attached Rubin et al patent no. 4,792,418 (Exhibit C) that extracts substantially 100% pure omega-3 fatty acids from fish oil. See also the discussion of the prior art in the Background section of this patent, referring to other patents and publications that purify omega-3 fatty acids from natural fish oil, particularly U.S. patent 4,377,526 and British patent 2,148,713.

Accordingly, it is urged that the production of fish oils with greater than 60% omega-3 PUFA was well within the skill of the art at the time that the present specification was filed. One example of a commercial product having this concentration is provided in the specification. More detailed disclosure is unnecessary when the purification of the fish oil is not part of the present invention, but the inventor is relying only on information, knowledge and products well known to the prior art at the time that the application was filed. As

pointed out in the Written Description Guidelines, information that is well known in the art need not be described in detail in the specification, see MPEP §2163 IIA.2. and MPEP §2163 IIA.3.(a), penultimate paragraph. Reconsideration and withdrawal of this rejection are, therefore, respectfully urged.

Claims 73, 86, 90 and 102 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. With respect to claim 73, 86 and 102, the examiner states that the limitation "omega-3 polyunsaturated fatty acids" has insufficient antecedent basis.

Claims 73 and 86 have now been amended so as to avoid this ground of indefiniteness. Claim 102 is dependent from claim 65, which recites omega-3 polyunsaturated fatty acids. Thus, claim 102 should be definite for the same reason that the examiner conceded that claim 65 was definite.

The examiner states that claim 90 recites the broad recitation "at least 50%" and also recites "at least 80%".

Claim 90 has now been amended in order to obviate this part of the rejection. Reconsideration and withdrawal of this rejection are, therefore, respectfully urged.

Claims 61-65, 70-73, 77-81, 84-92, 97-100 and 102 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Cain in view of Grace in further view of Moskowitz, Merck index and applicant's admission at page 7, lines 20-26, and page 12, lines 1-11, for the reasons of record in the previous Office action. The examiner states that the composition claimed by Cain is not limited to those

made by the particular sophisticated process mentioned by applicant. Further, the examiner states that the well-defined composition in Cain encompasses the claim herein with respect to the amount of omega-3 fatty acid, amount of liquid oil and solid fat. The examiner states that Grace is cited to show that it is known in the art that beeswax is known to be useful in fat-blend food products. The examiner states that Cain has shown that fish oil can be converted to spread by mixing with solid fat and that since beeswax is known to be useful in food-fat blends, and it is known to be solid, it would, therefore, be obvious to employ beeswax as the solid fat in Cain's composition. This rejection is respectfully traversed.

Claim 61 has now been amended to specify that the composition consists essentially of a mixture of at least one liquid oil and beeswax. The composition of Cain includes fish oil and a complementary fat, having a solid fat index at 10°C that is either at least 5% more at least 5% less than the solid fat index of the concentrate. At column 2, lines 20-23, the preferred complementary fats are disclosed as being:

cocoa butter equivalents, cocoa butter, palm oil or fractions thereof, palmkernel oil or fractions thereof, interesterified mixtures of above fats, or fractions or hardened components thereof.

There is no suggestion of the use of a wax as the complementary fat. While the British Grace patent discloses beeswax as a component of a food spread, there is no motivation to combine the teachings of Grace and Cain. The British patent states that the wax is used as part of the emulsifier composition. Thus, the composition of Grace is

disclosed at page 1, lines 59-75, as including from 50-74 parts water, from 26-50 parts fat and from 0.1-22 parts of an edible emulsifier composition, which comprises (1) from 0.6-10 parts wax, (2) 1-12 parts non-ionic emulsifier or emulsifier combination that yields a hydrophilic and lipophilic balance from 3-6, and from 100-25% by weight of lipophilic emulsifier. Thus, Grace requires fat, but beeswax is not an example of the fat. Beeswax is only disclosed as a part of the emulsifier. The fats are described by Grace at page 2, lines 13-29. There is no suggestion of using beeswax as a fat. The only place that beeswax is mentioned is at page 2, lines 39-42, which clearly discloses that the beeswax is used only in preparing the emulsifier.

One of ordinary skill in the art would have no motivation to use an emulsifier component as a substitute for the complementary fat of Cain. Cain does not use any kind of wax. Merely because a wax was used for an irrelevant purpose in some other butter does not make it obvious to use in any butter. There simply is no motivation to combine. Picking and choosing from references based on hindsight reconstruction of the invention is impermissible under 35 U.S.C. §103. See *Ex parte Levingood*, 28 USPQ2d 1300, 1301-1302 (Bd Pat Appl & Int 1993), where it states:

In this case, however, the only suggestion for the examiner's combination of the isolated teaching of the applied references improperly stems from appellant's disclosure and not from the applied prior art. ... At best, the examiner's comments regarding obviousness amount to an assertion that one of ordinary skill in the relevant art would

have been able to arrive at appellant's invention because he had the necessary skills to carry out the requisite process steps. This is an inappropriate standard for obviousness. ... That which is within the capabilities of one skilled in the art is not synonymous with obviousness. ... That one can reconstruct and/or explain the theoretical mechanism of an invention by means of logic and sound scientific reasoning does not afford the basis for an obviousness conclusion unless that logic and reasoning also supplies sufficient impetus to have led one of ordinary skill in the art to combine the teachings of the references to make the claimed invention.

...

Accordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one of ordinary skill in the art to do what the patent applicant has done.

Furthermore, the combination of liquid oil, particularly fish oil, and beeswax, provides some unexpected results not predictable from any combination of Cain and Grace. Beeswax has been reported to be an antioxidant -- see, for example, the attached pages of websites (Exhibits D-F), U.S. patent 5,858,425 (column 4) (Exhibit G), and WO 02/089846 (page 6) (Exhibit H) at the highlight portions. See also Mas, Drugs of the future, 28:731k-744 (2001), pages 731, 732, 734 and 735 of which are attached hereto (Exhibit I), relating to the antioxidant properties of a component of beeswax. Thus, beeswax helps to protect tissue from damage caused by free radicals and prevents oxidation of the fish oil. Beeswax has a neutral taste, contrary to other solid fats including those

previously claimed) that have a strong taste. A small amount of beeswax, much smaller than other solid fats, is sufficient for the solidification of the mixture. In addition, the solidified combination is very stable and the paste has a shelf life much longer than with other solid pastes, while maintaining the texture. A further advantage is that beeswax contains only a very small amount of the bountiful C16 and C18 saturated fatty acids, palmitic and stearic acid. Thus, the product of the present invention has important properties that would not be obvious from any reading of Cain and Grace.

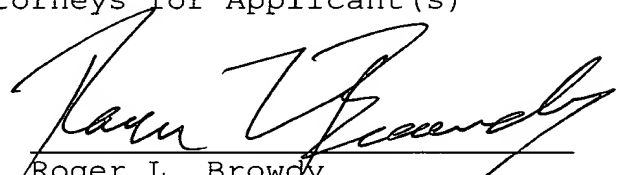
Accordingly, reconsideration and withdrawal of this rejection are respectfully urged.

It is submitted that all of the claims now present in the case clearly define over the references of record and fully comply with 35 U.S.C. §112. Reconsideration and allowance are, therefore, earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By


Roger L. Browdy
Registration No. 25,618

RLB:rd
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\B\BENA\Yaml\Pto\AmendmentD.doc